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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/936,205	SMITH ET AL.	
	Examiner	Art Unit	
	AGNES B. ROOKE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,16 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 16, and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Final office action is in response to the paper filed on 02/11/2008. Amendments to the claims filed on 02/11/2008 are acknowledged.

Status of Claims

Claims 9, 16, and 19-21 are pending and under consideration. Claims 1-8, 10-15, 17-18, and 22-24 are cancelled.

Rejections Withdrawn

The rejection of claims 9, 14, 16-22, and 24, under 35 USC 112, second paragraph, is withdrawn in view of the amendment to claim 9 and cancellation of claim 24.

The rejection of claims 9, 14, 16, 18-22, and 24, under 35 USC 112, first paragraph, in reference to the written description and scope of enablement are withdrawn in view of the amendments to claim 9 and cancellation of the rejected claims, since one skilled in the art would be able to practice the invention since the SCR1-3 structure is specifically pointed out in claim 16, as amended.

The rejection of claims 9, 14, 16, 17, and 19-22, under 35 USC 102(e) as being anticipated by Rittershaus et al. is withdrawn in view of the amendments to claim 9 and cancellation of claims 17 and 22. Further, Rittershaus et al. do not teach SCR1-3 that is conjugated to myristoyl.

The rejection of claims 9, 14, 16-21, and 24 under 35 U.S.C. 103(a) as being unpatentable over by Rittershaus et al. (U.S. 6,193,979 B1) in view of Smith et al. (U.S. 6,713,606 B1) is withdrawn because the amendment to claims 9 and 16 in regards to the language consists of" the SCR1-3 with specified sequence at positions 2 to 197 of SEQ ID NO:1. Also, Smith et al. anticipates claims 9 and 19-21 as amended. See rejection below.

Maintained rejections and new rejections necessitated by amendments to claims

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 16, and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite because it is unclear from the claim as presented where a particular basic amino acid sequence is present in the sequence according to SEQ ID NO:1? Also, the word “according” is not clear since it is not certain whether the basic amino acid sequence is SEQ ID NO:1 or is the basic amino acid sequence embedded in SEQ ID NO:1? Examiner reviewed the sequence listing in regards to the basic amino acid sequence according to SEQ ID NO:1 and no explanation or any information regarding the basic amino acid sequence is mentioned in the description of the SEQ ID NO:1. Therefore, the claim is indefinite and unclear as written.

Further, claim 9 is confusing as presented since the language is changing from open (i.e. "comprising" language that suggests additional sequences on both sides of the claimed fragment) to closed (i.e. consisting of " language that suggests the specific fragment only without additional sequences on either end). Thus, examiner suggests that the claims be amended to state: "wherein the soluble derivative consists of: a fragment of CR1 conjugated to myristoyl and a basic amino acid sequence of SEQ ID NO:1, wherein the CR1 fragment..." provided the a support in the original disclosure includes a basic amino acid sequence as SEQ ID NO:1, for example.

Further, claim 9 is indefinite because the claim is not properly defined as currently presented, for example, the word "the" is missing in between consist of" and "first three" to properly define the first three SCRs to define specific and particular pieces of SCR1-3.

Also, claim 9 contains the trademark/trade name SOLTRAN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the solution used and, accordingly, the identification/description is indefinite.

Dependent claims 16 and 19-21 are included in this rejection since they do not cure the deficiencies of base claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Smith et al**. (U.S. 6,713,606 B1) in view of the **Baxter SOLTRAN** solution product #FKB4708G (see a copy of the Baxter product attached to this office action) and **Varty et al.,** "Response to organ shortage: kidney retrieval programme using non-heart beating donors," BMJ 1994, volume 308, page 575 (See Abstract as attached to this office action). The change in the rejection to Smith et al. in view of the Baxter SOLTRAN solution product and Varty et al is necessitated by Applicant's amendment.

Smith et al. teach CR1 fragments that would inherently include a fragment of CR1-3. Further, Smith et al. teach soluble CR1 polypeptide that is derivatized with a myristoyl group (See column 17, line 55). At column 18, Smith et al. teach the use of peptides for Post-Ischemic Reperfusion Conditions. Thus, the reference clearly anticipates the invention as recited in claim 9.

Smith et al. does not specifically teach SOLTRAN solution.

As supporting evidence to the fact that SOLTRAN is a popular and widely used solution that is used as physiologically acceptable flush solution, examiner included in the instant office action a copy of the Baxter's product that is sold as SOLTRAN solution and is commonly used in perfusion procedures.

Varty et al. teach that SOLTRAN produced by Baxter company was used in perfusion for organ donation purposes. (See third paragraph of the Abstract, on page 575 as included).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method for preparing an organ by perfusion prior to transplantation or storage of the organ that uses soluble CR1 polypeptide which includes a CR1-3 fragment that is derivatized with a myristoyl group and to administer such peptides to a patient or a transplant prior to implantation as taught by Smith et al. and to use in such a method the SOLTRAN product that is commonly used as a physiologically acceptable flush solution used in perfusion procedures as taught by Varty et al. One skilled in the art would be motivated to design such a method when SOLTRAN is utilized because such physiological solutions are commonly used in transplanting of different organs and preventing rejection of such organs. Therefore, the invention is *prima facie* obvious.

Applicants argue that Smith discloses compositions including CR1 fragments for treatment of injury which has occurred by ischemic conditions and that the present invention is intended to pre-treat "healthy" organs before transplant/storage so as to prevent ischemic injury. Further, Applicants state that Smith et al. disclose soluble

derivatives of soluble peptides and the present claims are not solely directed to such composition or derivatives but rather inventive selection. Further, Applicants state that SOLTRAN is used in the method.

Examiner maintains the rejection because in column 19, lines 60-67, Smith et al. teach a method of delaying hyperacute allograft or hyperacute xenograft rejection in a human or non-human, which receives a transplant by administering an effective amount of a soluble complement inhibitor, such as soluble CR1 polypeptide and derivative, where such administration maybe to the patient or by application to the transplant prior to implantation. Therefore, Smith et al. teach administration of CR1 fragments or derivatives to patients before surgery or to the organs to be transplanted themselves (instant claims 19-21). Also, in regards to SOLTRAN, it is a physiologically acceptable flush solution that is routinely used during perfusion procedures and the name itself is trademarked.

Further, examiner would like to point out that the sequence of SCR1 is not specified in claim 9 and that the peptides of Smith et al. will inherently contain such a sequence that would have a function of complement inhibitory activity, and thus be effectively used in the method of preparing organ prior to transplantation or storage. Furthermore, the peptides or derivatives of Smith et al. are conjugated to myristoyl, as claimed in amended claim 9.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have

any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Kathleen Kerr Bragdon/

Supervisory Patent Examiner, Art Unit 1656